

902 KAR 100:070. Transportation of radioactive material.

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 71, 73, 39 C.F.R. 111.1, 49 C.F.R. 107, 170-189

STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary to promulgate those administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. KRS 211.844 requires the Cabinet for Health and Family Services to promulgate administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes requirements for transportation of radioactive material.

Section 1. Applicability. (1) Applies to a licensee authorized by a specific or general license issued by the cabinet to receive, possess, use, or transfer radioactive material, when:

- (a) The licensee delivers that material to a carrier for transport;
 - (b) Transports the material outside the site of usage as specified in the cabinet license; or
 - (c) Transports the material on public highways.
- (2) This administrative regulation shall not authorize the possession of radioactive material.

Section 2. Requirement for a License. A person shall not deliver radioactive material to a carrier for transport, or transport radioactive material, unless:

- (1) Authorized in a general or specific license issued by the cabinet; or
- (2) Exempted pursuant to Section 3 of this administrative regulation.

Section 3. Exemptions. (1) A licensee is exempt from all the requirements of this administrative regulation with respect to shipment or carriage of the following low-level materials:

- (a) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, if the activity concentration of the material does not exceed ten (10) times the values specified in 10 C.F.R. 71, Appendix A; and
- (b) Materials for which the activity concentration is not greater than the activity concentration values, or for which the consignment activity is not greater than the limit for an exempt consignment found in 10 C.F.R. 71, Appendix A.

(2) A physician licensed by the Commonwealth to dispense drugs in the practice of medicine shall be exempt from Section 4 of this administrative regulation with respect to transport by the physician of radioactive material for use in the practice of medicine. However, a physician operating under this exemption shall be licensed pursuant to 902 KAR 100:072 or equivalent regulations of the NRC or an agreement state.

Section 4. Transportation of Licensed Material. (1) Each licensee who transports licensed material outside of the confines of his plant or other place of use specified in the cabinet license, or if transport is on a public highway, or who delivers licensed material to a carrier for transport, shall:

- (a) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation in 49 C.F.R. 107, 171 through 180, and 390 through 397; and

(b) Assure that special instructions needed to open the package safely are sent to, or have been made available to, the consignee for the consignee's use in accordance with 902 KAR 100:019, Section 28(5).

(2) If the regulations of the U.S. Department of Transportation (DOT) are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the Department of Transportation regulations, specified in subsection (1)(a) of this section, to the same extent as if the shipment was subject to the DOT regulations.

Section 5. General Licenses for Carriers. (1) A general license shall be issued to a common or contract carrier, not exempt under Section 3 of this administrative regulation, to receive, possess, transport, and store radioactive material in the regular course of carriage for another, or storage incident to the transportation and storage, if the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation relating to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(2) A general license shall be issued to a private carrier to transport radioactive material, if the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation relating to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(3) The notification of incidents referred to in the U.S. Department of Transportation requirements identified in subsection (1) of this section shall be filed with, or made to, the cabinet.

(4) A person authorized by a general license described in this section, who transports radioactive material, is exempt from the requirements of 902 KAR 100:019 and 902 KAR 100:165.

Section 6. General License: NRC Approved Packages. (1) A general license shall be issued to a licensee of the cabinet to transport or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(2) The general license shall apply only to a licensee who:

(a) Has a quality assurance program approved by the NRC as satisfying the provisions of 10 C.F.R. 71.101 through 137;

(b) Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(c) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137; and

(d) Submits in writing to Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, using an appropriate method listed in 10 C.F.R. 71.1(a), before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.

(3) The general license identified in subsection (1) of this section shall apply only if the package approval authorizes use of the package under the general license.

(4) For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license shall be subject to additional restrictions contained in Section 7 of this administrative regulation.

Section 7. Previously Approved Type B Packages. (1) A Type B package previously approved by the NRC, but not designated as B(U) or B(M) in the NRC Certificate of Compliance, may be used under the general license of Section 6 of this administrative regulation, with the following limitations:

(a) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by its model number, in accordance with NRC regulations;

(b) The package shall not be used for a shipment to a location outside the United States after August 31, 1986, except under multilateral approval by the U.S. Department of Transportation, as defined in 49 C.F.R. 173.403; and

(2) A serial number that uniquely identifies each package that conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each package.

(3) A Type B(U) package, a Type B(M) package, an LSA material package, or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC Certificate of Compliance, may be used under the general license of Section 6 of this administrative regulation, with the following conditions:

(a) Fabrication of the package shall have been satisfactorily completed by April 1, 1999, as demonstrated by its model number, in accordance with NRC regulations, 10 C.F.R. 71;

(b) A package used for shipment to a location outside the United States shall be subject to multilateral approval by the U.S. Department of Transportation, as defined in 49 C.F.R. 173.403; and

(c) A serial number that uniquely identifies each package that conforms to the approved design shall be assigned to, and legibly and durably marked on the outside of, each package.

Section 8. General License: DOT Specification Container. (1) A general license shall be issued to a licensee of the cabinet to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material, or for a Type B quantity of radioactive material, as specified in 49 C.F.R. Parts 173 and 178.

(2) The general license shall apply only to a licensee who:

(a) Has a quality assurance program approved by the cabinet as satisfying the requirements of 10 C.F.R. 71.101 through 71.137;

(b) Has a copy of the specification; and

(c) Complies with the terms and conditions of the specification, and the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137.

(3) The general license shall be subject to the limitation that the specification container shall not be used for a shipment to a location outside the United States except by multilateral approval, as defined in 49 C.F.R. 173.403.

(4) This section expires October 1, 2008.

Section 9. General License: Use of Foreign Approved Package. (1)(a) A general license shall be issued to a licensee of the cabinet to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate and revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 C.F.R. 171.12.

(b) Except as provided in this section, the general license shall apply only to a licensee who has a quality assurance program approved by the NRC as satisfying the applicable provisions of 10 C.F.R. 71.101 through 71.137.

(2) The general license shall apply only to shipments made to or from locations outside the United States.

- (3) The general license shall apply to a licensee who:
- (a) Has copies of the applicable certificate, the revalidation, the drawings, and other documents referenced in the certificate relating to the:
 - 1. Use and maintenance of the packaging; and
 - 2. Actions to be taken prior to shipment; and
 - (b) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137.
- (4) With respect to the quality assurance provisions of 10 C.F.R. 71.101 through 71.137, the licensee shall be exempt from design, construction, and fabrication considerations.

Section 10. Preliminary Determinations. Before the first use of a packaging for the shipment of radioactive material:

- (1) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that may significantly reduce the effectiveness of the packaging;
- (2) If the maximum normal operating pressure will exceed thirty-five (35) kilopascal (five (5) lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least fifty (50) percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure; and
- (3) The licensee shall mark the packaging, conspicuously and durably, with its model number, serial number, gross weight, and a package identification number assigned by the NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

Section 11. Routine Determinations. Before making a shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this administrative regulation and of the license. The licensee shall determine that:

- (1) The package is proper for the contents to be shipped;
- (2) The package is in unimpaired physical condition except for superficial defects, such as marks or dents;
- (3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
- (4) A system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
- (5) A pressure relief device is operable and set in accordance with written procedures;
- (6) The package has been loaded and closed in accordance with written procedures;
- (7) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;
- (8) A structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by 10 C.F.R. 71.45.
- (9) The level of nonfixed, or removable, radioactive contamination on the external surfaces of each package offered for shipment is ALARA, and within the limits specified by the U.S. Department of Transportation in 49 C.F.R. 173.443;
- (10) External radiation levels around the package and around the vehicle, if applicable, shall not exceed the limits specified in 49 C.F.R. 71.47 during transportation.
- (11) Accessible package surface temperatures shall not exceed the limits specified in 10 C.F.R. 71.43(g) at any time during transportation.

Section 12. Air Transport of Plutonium. In addition to the requirements of a general license and exemptions stated in this administrative regulation or included by citation of U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

- (1) The plutonium is contained in a medical device designed for individual human application;
- (2) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in 10 C.F.R. 71, Appendix A and in which the radioactivity is essentially uniformly distributed;
- (3) The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in an isotope or form and is shipped in accordance with Section 4 of this administrative regulation;
- (4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC; or
- (5) For a shipment of plutonium by air which is subject to subsection (4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 C.F.R. 175.704, applicable to the air transport of plutonium;
- (6) Nothing in this section shall be interpreted as removing or diminishing the requirements of 10 C.F.R. 73.24.

Section 13. Advance Notification of Transport of Irradiated Reactor Fuel and Nuclear Waste.

- (1)(a) Before the transport of nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or before the delivery of nuclear waste to a carrier for transport, a licensee shall provide advance notification of the transport to the governor, or governor's designee, of each state through which the waste will be transported.
- (b) Advance notification shall be required for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements in 10 C.F.R. 73.37(f).
- (2) Advance notification shall also be required for licensed material, other than irradiated fuel, if:
 - (a) The nuclear waste is required to be in Type B packaging for transportation;
 - (b) The nuclear waste is being transported to, through, or across a state boundary to a disposal site, or to a collection point for transport to a disposal site; and
 - (c) The quantity of licensed material in a single package exceeds the least of the following:
 1. 3,000 times the A₁ value of the radionuclides as specified in 10 C.F.R. 71, Appendix A for special form radioactive material;
 2. 3,000 times the A₂ value of the radionuclides as specified in 10 C.F.R. 71 Appendix A for normal form radioactive material; or
 3. 27,000 curies (1000 TBq).
- (3) Each advance notification shall be in writing and contain the following information:
 - (a) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
 - (b) A description of the nuclear waste contained in the shipment as required by 49 C.F.R. 172.202 and 172.203(d);
 - (c) The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;
 - (d) The seven (7) day period during which arrival of the shipment at state boundaries is estimated to occur;

(e) The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and

(f) A point of contact with a telephone number for current shipment information.

(4) The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the cabinet.

(a) A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

(b) A notification delivered by messenger shall reach the office of the governor, or governor's designee, at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three (3) years.

(5) The licensee who finds that schedule information previously furnished will not be met, shall telephone a responsible individual in the office of the governor, or governor's designee, and the cabinet and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain for three (3) years a record of the name of the individual contacted.

(6) A licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the cabinet. The licensee shall state in the notice that it is a cancellation and shall identify the advance notification that is being cancelled. A copy of the notice shall be retained by the licensee for three (3) years.

Section 14. Exemption from Classification as Fissile Material. Fissile material meeting the requirements of at least one (1) of the subsections (1) through (6) of this section are exempt from classification as fissile material and from the fissile material package standards of 10 C.F.R. 71.55 and 71.59, but are subject to all other requirements of this administrative regulation, except as noted. (1) Individual package containing two (2) grams or less fissile material;

(2) Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material;

(3)(a) Low concentrations of solid fissile material commingled with solid nonfissile material, if:

1. There is at least 2,000 grams of solid nonfissile material for every gram of fissile material; and

2. There is no more than 180 grams of fissile material distributed within 360 kilograms of contiguous nonfissile material.

(b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and with total plutonium and uranium content of up to one (1) percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five (5) percent of the uranium mass;

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two (2) percent by mass, with a total plutonium and uranium-233 content not exceeding two one-thousandths (0.002) percent of the mass of uranium, and with a minimum nitrogen to uranium

atomic ratio (N/U) of two (2). The material shall be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than twenty (20) percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

Section 15. General License: Fissile Material (1) A general license is issued to any licensee of the cabinet to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section of this administration regulation. The fissile material need not be contained in a package which meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).

(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71.101 through 71.137.

(3) The general license shall apply only when a package's contents:

(a) Contain less than a Type A quantity of radioactive material; and

(b) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(4) The general license shall apply only to packages containing fissile material that are labeled with a Criticality Safety Index (CSI) that:

(a) Has been determined in accordance with subsection (5) of this section;

(b) Has a value less than or equal to ten (10); and

(c) For a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance, and less than or equal to 100, for shipment on an exclusive use conveyance.

(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left(\frac{\text{grams of U-235}}{X} + \frac{\text{grams of U-233}}{Y} + \frac{\text{grams of Pu}}{Z} \right)$$

(b) The calculated CSI shall be rounded up to the first decimal place;

(c) The values of X, Y, and Z used in the CSI equation shall be taken from 10 C.F.R. Tables 71 - 1 or 71 - 2, as appropriate;

(d) If 10 C.F.R. Table 71 - 2 is used to obtain the value of X, then the values of the terms in the equation for uranium-233 and plutonium shall be assumed to be zero (0); and

(e) 10 C.F.R. Table 71 - 1 values for X, Y, and Z shall be used to determine the CSI if:

1. Uranium-233 is present in the package;

2. The mass of plutonium exceeds one (1) percent of the mass of uranium-235;

3. The uranium is of unknown uranium-235 enrichment or greater than twenty-four (24) percent enrichment; or

4. Substances having a moderating effectiveness (an average hydrogen density greater than water), such as certain hydrocarbons oils or plastics, are present in any form, except as polyethylene used for packaging or wrapping.

Section 16. General License: Plutonium-beryllium Special Form Material. (1) A general license is issued to any licensee of the cabinet to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section of this administrative

regulation. This material need not be contained in a package which meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).

(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71 Subpart H.

(3) The general licensee applies only if a package's contents:

(a) Contain less than a Type A quantity of radioactive material; and

(b) Contain less than 1,000 grams of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

(4) The general license applies only to packages labeled with a CSI that:

(a) Have been determined in accordance with subsection (5) of this section;

(b) Have a value less than or equal to 100; and

(c) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance and less than or equal to 100, for shipment on an exclusive use conveyance.

(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left(\frac{\text{grams of Pu-239} + \text{grams of Pu-241}}{24} \right)$$

(b) The calculated CSI shall be rounded up to the first decimal place.

Section 17. External Radiation Standards for all Packages. (1) Except as provided in subsection (2) of this section, a package of radioactive materials offered for transportation shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level shall not exceed 200 millirem/hour (mrem/h) (2 millisieverts/h) (2 mSv/h) at any point on the external surface of the package, and the transport index shall not exceed ten (10).

(2) A package that exceeds the radiation level limits specified in subsection (1) of this section shall be transported by exclusive use shipment only, and the radiation levels for the shipment shall not exceed the following during transportation:

(a) 200 mrem/h (2 mSv/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 1,000 mrem/h (10 mSv/h);

1. The shipment is made in a closed transport vehicle;

2. The package is secured within the vehicle so that its position remains fixed during transportation; and

3. There are no loading or unloading operations between the beginning and end of the transportation;

(b) 200 mrem/h (2 mSv/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or in case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(c) 1. Ten (10) mrem/h (0.1 mSv/h) at any point eighty (80) inches (2 meters) from the outer lateral surface of the vehicle, excluding the top and underside of the vehicle; or

2. In the case of a flat-bed style vehicle, at any point six and six tenths (6.6) feet (2 meters) from the vertical planes projected by the outer edges of the vehicle, excluding the top and underside of vehicle; and

(d) Two (2) mrem/h (0.02 mSv/h) in any normally occupied space, except that this provision shall not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices as required by 902 KAR 100:019, Section 13.

(3) For shipments made under the provisions of subsection (2) of this section, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions shall be included with the shipping paper information.

(4) The written instructions required for exclusive use shipments shall be sufficient so that, if followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposure to transport workers or members of the general public.

Section 18. Assumption as to Unknown Properties. If the isotopic abundance, mass, concentration, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

Section 19. Opening Instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 902 KAR 100:019, Section 28(5).

Section 20. Quality Assurance Requirements. (1) The requirements in Sections 20 through 28 shall apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging important to safety. As used in this administrative regulation, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

(2) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(3) The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging.

(4) A licensee is responsible for the quality assurance provision that applies to its use of a packaging for the shipment of licensed material subject to this administrative regulation.

(5) A licensee, certificate holder, and applicant for a CoC shall:

(a) Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 C.F.R. 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and

(b) Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(6) A licensee shall, before the use of a package for the shipment of licensed material subject to this administrative regulation, obtain U.S. Nuclear Regulatory Commission approval of its quality assurance program. Using an appropriate method listed in 10 C.F.R. 71.1(a), a licensee shall file a description of its quality assurance program, including a discussion of which requirements of this administrative regulation are applicable and how they will be satisfied, by

submitting the description to: Attention: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

(7) A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 902 KAR 100:100, Section 9(3) shall satisfy the requirements of Section 6(2)(a) and subsection (5) of this section.

Section 21. Quality Assurance Organization. (1) The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities shall include performing the functions associated with attaining quality objectives and the quality assurance functions.

(2) The quality assurance functions shall:

(a) Assure an appropriate quality assurance program is established and effectively executed; and

(b) Verify, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(3) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to:

(a) Identify quality problems;

(b) Initiate, recommend, or provide solutions; and

(c) Verify implementation of solutions.

(4) While the term "licensee" is used, the requirements in this section shall be applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.

Section 22. Quality Assurance Program. (1) The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 C.F.R. 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions shall include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment,

tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following conditions concerning the complexity and proposed use of the package and its components:

- (a) The impact of malfunction or failure of the item to safety;
- (b) The design and fabrication complexity or uniqueness of the item;
- (c) The need for special controls and surveillance over processes and equipment;
- (d) The degree to which functional compliance can be demonstrated by inspection or test;

and

- (e) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary, to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

Section 23. Handling, Storage, and Shipping Control. The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. If necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels shall be specified and provided.

Section 24. Inspection, Test and Operating Status. (1) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures shall provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by passing of the inspections and tests.

(2) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Section 25. Nonconforming Materials, Parts, or Components. The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Section 26. Corrective Action. The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. If a significant condition adverse to quality exists, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the

corrective action taken shall be documented and reported to appropriate levels of management.

Section 27. Quality Assurance Records. (1) The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records shall include the instructions, procedures, and drawings required by 10 C.F.R. 71.111 to prescribe quality assurance activities and shall include closely related specifications such as required qualifications of personnel, procedures, and equipment.

(2) The records shall include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.

(3) The licensee, certificate holder, and applicant for a CoC shall retain these records for three (3) years beyond the date when the licensee, certificate holder, applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for CoC shall retain the superseded material for three (3) years after it is superseded.

Section 28. Audits. (1) The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

(2) The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.

(3) Audited records shall be documented and reviewed by management having responsibility in the area audited.

(4) Follow-up action, including reaudit of deficient areas, shall be taken as indicated.

Section 29. Determination of A_1 and A_2 . Values of A_1 and A_2 shall be determined as described in 10 C.F.R. 71 Appendix A. (1 Ky.R. 403; eff. 2-5-1975; Am. 2 Ky.R. 479; eff. 4-14-1976; 12 Ky.R. 1044; eff. 1-3-1986; 13 Ky.R. 1769; eff. 5-14-1987; 18 Ky.R. 1525; eff. 1-10-1992; 26 Ky.R. 2402; 27 Ky.R. 976; eff. 10-16-2000; 37 Ky.R. 1827; 2618; eff. 6-3-2011; 41 Ky.R. 914; 1606; eff. 2-5-2015.)